REGULATORY COMPLIANCE

Policy & Procedures

SUSPICIOUS ORDER REPORTING

PURPOSE

DEA regulation, 21 CFR 1301.74(b), states: "The registrant shall *design and operate a system to disclose to the registrant suspicious orders of controlled substances.*"

DEA regulation, 21 CFR 1301.74(b), defines a suspicious order as follows: "Suspicious orders *include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.*"

In addition to reporting "suspicious orders" The Methamphetamine Control Act has a retail-reporting threshold of 24 grams for products containing ephedrine or pseudoephedrine. Therefore, *retail sale (at one time) of 800 x 30mg or 400 x 60mg (or more) pseudoephedrine tablets to one customer is required to be reported to the DEA.*

POLICY

The Risk Management Department will assist DC's in ensuring that all suspicious order reporting takes place and that these reports are transmitted to the appropriate DEA office.

OVERVIEW OF PROCEDURE

The AS400 system automatically reports suspicious orders of CDS and Listed Chemical (LC) product to your local DEA office via the automated suspicious order reporting system. Please contact your local DEA office to verify they are receiving suspicious order reports from your Distribution Center.

This procedure meets all regulatory requirements and has been approved by the DEA's Chief Liaison and Policy Section Office of Diversion Control. A copy of this approval letter should be maintained at your Distribution Center with your DEA documents file. A copy of the approval letter can be obtained from the Risk Management Group.

Distribution Centers should never complete a transaction for a product that involves an uncommon method of payment or delivery.

PLAINTIFFS TRIAL EXHIBIT
P-00953_00001

REGULATORY COMPLIANCE

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If a customer or DEA contacts your Distribution Center regarding a "suspicious order" you should contact the Risk Management Department at the General Office for assistance.